Medical Device Incident Investigations: Recommendations

Oxylog 2000

Safety alert: check the circuit before use and be familiar with the instructions for use

The Therapeutic Goods Administration recently investigated a report following an adverse event with an Oxylog 2000. The report stated that during a transfer the ventilator was not generating pressure. The patient was not adequately ventilated and their condition deteriorated, leading to a cessation of the resuscitation attempt.

Investigation of the ventilator and circuit found that a valve had being placed upside down in the circuit. The valve had been put in the wrong way during cleaning and reassembly and was not detected until the users began troubleshooting when the ventilator continued an alarm. The issue was further compounded by procedural errors and the ventilator issuing two alarms at the same time.

The ventilator circuit is available as either reusable or single use. In this case the circuit was reusable and was cleaned and reassembled following use. The instructions for assembling the device are well laid out in the instruction manual. The manual also instructs the assembler and/or user to test the circuit prior to use and at regular intervals. The investigation into this event found that reference to the instructions and testing of the circuit following assembly or by the user does not appear to have been conducted.

Alarm situations where there are two causes could happen at any given time. The alarm with the highest priority will be indicated by an audible alarm, a flashing red light and visual display. If the alarm reset button is pushed to silence the alarm, the alarm will be silent for two minutes if the lower priority problem has been corrected instead of the higher alarm. However, there will still be visual indicators such as the red light continuing to flash and the ventilator's display screen indicating that there is still a problem.

The manufacturer has confirmed that the alarm with the highest priority will be displayed on the monitor and, if fixed, any other alarm issues of lesser priority will initiate a new alarm regardless of the button being muted.

The *Instructions for Use* (IFU) also have a detailed list of alarm codes and the remedies for these codes which users should be familiar with.

Recommendations

The TGA recommends that users of these devices familiarise themselves with the manufacturer's *Instructions for Use* (IFU) and that CSSD departments should ensure that the cleaning and assembling of these devices follows the instructions for use. Both users and CSSD department should ensure that the device is checked following assembly and at regular intervals, as stated in the IFU:

- Whenever the breathing valve is changed
- Whenever the ventilator has been stripped down/assembled
- Prior to use
- At least every six months

Documentation of these checks is also advised. The TGA recommends that users become familiar with this list of alarm codes and remedies.

What is the medical device incident reporting investigation scheme?

The medical device incident reporting scheme has recently been expanded to become a joint venture between the Australian Therapeutic Goods Administration and Medsafe, the New Zealand Medicines and Medical Devices Safety Authority. The aim of the scheme is to improve the standard of medical devices and to reduce the number and severity of incidents with devices in Australia and New Zealand.

A new incident report form has been adopted to reflect the joint venture and an advertising campaign is on the way to encourage medical device users and manufacturers or their representatives to report problems associated with the use of medical devices.

While suppliers and/or manufacturers are responsible for their products, the scheme can play an important role in ensuring effective and efficient resolution or prevention of incidents.

If you purchase, use or maintain medical devices, you are encouraged to report incidents or difficulties associated with their use.

What is a medical device?

A medical device is any material, instrument, machine, appliance, implant or component of these used in the delivery of health care, other than a medicine.

What should be reported?

Always report any incident that has caused, or could have caused, an injury to the patient or the device user. In Australia, reporting of such events by suppliers and manufacturers is mandatory.

In addition to reporting safety issues, everyone is encouraged to report any issues of the quality and efficacy of medical devices. Such examples include compromised sterility, packaging or labelling defects and poor construction or design.

How are these reports investigated?

A panel of scientific, engineering and clinical experts assesses all reports. The panel recommends what level of investigation will take place.

Reports of incidents that have led, or are likely to lead, to serious injury are given the highest priority. Unusual incidents, incidents that may have led to injury, or incidents that have unusually high levels of incidence are routinely investigated. Isolated incidents or incidents that are not likely to lead to any injury or have a detrimental effect on effectiveness are not investigated. All reports are entered into the Scheme's database so that they may be easily referenced in the future.

Once a report has been recommended for investigation, it is assigned to the most appropriately-qualified investigator. The investigator will contact the company, and continues to work with the company and the reporter to resolve any issue.

Reports are treated confidentially and both the reporter and the supplier are informed of the outcome of the investigation.

Final outcomes may include Recall, Safety alert, Product improvement, Compliance testing, User education or an article in the Therapeutic Device Bulletin.

Australia's TGA and New Zealand's Medsafe exchange information on any significant incident investigations.

How to submit an incident report

In Australia, please forward your incident report to:

Reply Paid 100
The Manager
Medical Device Incident Report Investigations
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606
Fax: 02 6232 8555
Email: iris@tga.gov.au

Urgent incidents may be reported by telephone to our HOTLINE: 1800 809 361

To request incident report forms, please call 02 6232 8695

In New Zealand, please forward your incident report to:

Compliance Team
Therapeutics Section
Ministry of Health
PO Box 5013
Wellington
NEW ZEALAND
Fax: 04 496 2599
Email: trevor_nisbet@moh.govt.nz

Urgent incidents may be reported by telephone on 04 496 2364

Risks of burns during MRI scans from transdermal drug patches with metallic backings

The Therapeutic Goods Administration (TGA) recently received notification from the US Food & Drug Administration (FDA) of an issue identifying the risk of burns to people who are wearing transdermal drug patches that have metallic backings while having an MRI scan. Some patches have a warning about this complication, yet others do not.

Transdermal patches slowly deliver medicines through the skin. Some patches contain metal in the backing, which may not be visible. Patches that contain metal, although not attracted to the magnetic field of the MRI, can overheat during an MRI scan and cause skin burns in the immediate area of the patch.

It is recommended that:

- Healthcare professionals referring patients for an MRI scan should inform the patient that the patch needs to be removed prior to the scan. The healthcare professional should advise these patients about the procedures for removing and disposing of the patch before the MRI scan, and replacing the patch after the MRI scan.
- MRI facilities need to be aware of this issue and check that patients are not wearing metal-backed patches prior to the scan.

Healthcare Professionals subscription page

This subscription page is managed by the Market Vigilance and Monitoring Section (MVMS) of the Office of Devices, Blood and Tissues, who has the responsibility for incident investigation and monitoring the safety of medical devices on the Australian market.

Healthcare professionals who subscribe to this service will receive information and advice about medical devices to assist with diagnosing, treating and/or managing their patients' medical conditions. This list will also increase awareness of the use of medical devices through:

- Product Recalls
- Hazard Alerts
- General safety information about medical devices, including links to news articles
- Advice that can arise from investigations into reports about problems or adverse events that occur with the use of medical devices

<http://www.tga.gov.au/problem/mdmvm-subscribe.htm>

FreeCall: 1800 809 361

MEDICAL DEVICE INCIDENT REPORT INVESTIGATION SCHEME (IRIS) STATISTICS REPORT 01/10/2008 to 31/12/2008
Total Number Received: 397

Cause of Problem[1]	
Component Failure	19
Contamination	4
Design	14
Electrical	54
Inadequate Instructions	2
Labelling	1
Maintenance	3
Manufacture	12
Material/Formulation Deficiency	5
Mechanical	168
Not Device Related	40
Other	13
Packaging/Sterility	4
Quality Assurance	4
Unknown	67
Wear/Deterioration	7

Effect	
Death	7
Serious Injury	150
Temporary Injury	92
No Injury	148

Source Category	
Medical Administrator	16
Specialist	14
General Practitioner	5
Nurse	27
Blood Bank	2
Hospital Supply Service	2
Other	17
Sponsor	292
Overseas Advice	1
Biomed Engineer	15
Para Medical	2
Patient/user	4
Dentist	0
Coroner	0

Result of Investigation	
Bulletin Article	5
Company Warned	1
Compliance Testing	0
No Further Action	124
Not Investigated[3]	220
Other	6
Problem Not Confirmed	4
Product Improvement	26
Recall/Hazard Alert	4
Safety Alert	12
User Education	35

Notes:

1. The problem causes are not mutually exclusive. For example, a material deficiency may have led to a mechanical malfunction or a biocompatibility problem.
2. Every report received by IRIS receives a risk analysis by the Scheme Coordinator and is discussed by a panel of technical and clinical professionals. In the case of reports that are "Not Investigated" the panel has made a decision that further investigation of the particular event is not necessary at that time. However, these reports are logged into the database for future reference and the trend of reports is monitored. In making their decision, the panel considers whether any similar reports have been received previously.